EXHIBIT A

From: Fenton, Christopher (CRM)
To: O"Neil, Benjamin A.; Bennett, Kayla (CRM); Zelinsky, Aaron (USAMD); Archer, Lauren (CRM)
Cc: doug.davison@linklaters.com; nicole.jerry@linklaters.com; Lurie, Adam; Cowley, Jason H.; Burton, Caroline Schmidt; Givens, Justin P; Reardon, Clare E.
Subject: Re: Kazempour
Date: Monday, October 16, 2023 9:58:12 PM

****EXTERNAL EMAIL; use caution with links and attachments****

Ben -

As I mentioned when we spoke earlier today, and as set forth below, the government does not believe the cases you rely on in your letter support the relief Dr. Kazempour seeks. We remain open to considering any other cases you would like to send to us for our consideration. If not, and should you decide to file a motion, we respectfully request the opportunity to meet and confer about a briefing schedule. Thank you.

On Oct 6, 2023, at 6:58 PM, Fenton, Christopher (CRM) <Christopher.Fenton@usdoj.gov> wrote:

Ben –

We reviewed your letter and will send a written response next week. In the meantime, I wanted to share that we do not agree that having an agent from FDA's Office of Criminal Investigations on the prosecution team means that the FDA is a part of the prosecution team. If you are aware of specific cases where a court made such a finding, please send them our way. In addition, we do not agree that because the prosecution team obtained certain documents from the FDA and interviewed some FDA witnesses, that the prosecution team then has an obligation (or ability) to conduct the broad search of the FDA's files requested in your letter. Again, if you are aware of authority that is directly on-point, we will of course take a look. If you think it would be potentially helpful to have a conference call to meet and confer, we are of course available. Either way, we will send a written response to your letter next week. Thank you and have a nice holiday weekend.

From: O'Neil, Benjamin A. <BONeil@mcguirewoods.com>
Sent: Monday, September 18, 2023 2:08 PM
To: Fenton, Christopher (CRM) <Christopher.Fenton@usdoj.gov>; Bennett, Kayla (CRM)

<Kayla.Bennett@usdoj.gov>; Zelinsky, Aaron (USAMD) <AZelinsky@usa.doj.gov>; Archer, Lauren (CRM) <Lauren.Archer2@usdoj.gov>
Cc: doug.davison@linklaters.com; nicole.jerry@linklaters.com; Lurie, Adam <adam.lurie@linklaters.com>; Cowley, Jason H. <JCowley@mcguirewoods.com>; Burton, Caroline Schmidt <CBurton@mcguirewoods.com>; Givens, Justin P <jgivens@mcguirewoods.com>; Reardon, Clare E. <CReardon@mcguirewoods.com>
Subject: [EXTERNAL] Kazempour

Counsel – please see the attached correspondence. Thanks.

Ben

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September 15, 2023

VIA EMAIL
Christopher Fenton
U.S. Department of Justice, Fraud Section
1400 New York Ave., N.W.
Washington, D.C. 20530
Christopher.Fenton@usdoj.gov

Re: *United States v. Kazem Kazempour*, No. 22-cr-440

Counsel:

Our review of discovery to date indicates that the government has produced very few internal communications or documents from the Food and Drug Administration (FDA) related to CytoDyn's biologic license application (BLA) submission.

To the extent the government has yet to review the FDA's files for such materials, we write to request that the government do so immediately. In particular, we request that the government search for and produce all internal FDA communications related or referring to CytoDyn's BLA submission, including but not limited to, the timing of the BLA submission, the defendants' roles and responsibilities with respect to the BLA submission, CytoDyn's press releases concerning Leronlimab, the process by which the FDA determined it would refuse to file the BLA, and the opinions of FDA reviewers of the BLA submission, CytoDyn and Amarex.

The discovery produced thus far strongly suggests that these types of materials exist but have yet to be produced. In particular, the February 8, 2022 FDA-OCI Memorandum of Interview of FDA employee Virginia Sheikh and the October 13, 2022 FDA-OCI Memorandum of Interview of FDA employee Suzanne Strayhorn indicate that Ms. Sheikh and Ms. Strayhorn were intently focused on CytoDyn as Leronlimab was being evaluated and undoubtedly would have communicated around these topics with colleagues.[1]

[1] *See* October 13, 2022 FDA-OCI Memorandum of Interview of FDA employee Suzanne Strayhorn, that states the FDA had been looking at Cytodyn's press releases since 2016, that it was "unusual for the FDA to follow sponsors' public statements," that Ms. Strayhorn "more than everybody else, followed this company outside of the FDA because of the statements that were being made," and that "it is dangerous to put misinformation and pump up a drug when sick people are dying, relatives are dying…it was a very scary time." The report also states Ms. Strayhorn "watched many videos of interviews put out by CYTODYN," that [those videos] were "more entertaining than the real housewives," and that it was "pretty unusual" to do so and that "she had never done it before."; *see also* February 8, 2022 FDA- OIC Memorandum of FDA employee Virginia Sheikh, that states Cytodyn's press release regarding the

It is the obligation of the government to turn over all exculpatory evidence to the defense and, upon request, to produce all information in the government's possession or control that is material to the preparation of a defense. *See* Fed. R. Crim. P. 16; *Brady v. Maryland*, 373 U.S. 83 (1963). Specifically, the government's discovery obligations apply to all members of the prosecution team, including federal, state, and local law enforcement officers and other government officials participating in the investigation and prosecution of the criminal case against the defendant. *See Kyles v. Whitley*, 514 U.S. 419, 437 (1995) (In order to comply with *Brady*, "the individual prosecutor has a duty to learn of any favorable evidence known to the others acting on the government's behalf…"); *Strickler v. Greene*, 527 U.S. 263, 280-81 (1999) (same); *U.S. v. Robinson*, 627 F.3d 941, 951 (4th Cir. 2010) (same).[2]

Here, those obligations apply to the FDA, an agency that is clearly part of the prosecution team,[3] as evidenced most plainly by the participation of special agents of the FDA's Office of Criminal Investigations in no less than 38 interviews during the investigation of this matter.[4]

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submitted BLA was the reason Susan Strayhorn sent Cytodyn the late April 2020 letter explaining to Cytodyn that the BLA submission was not complete. Ms. Sheikh further stated that it was "not typical for the FDA to look for press releases as part of their interview Process," that looking for those press releases was "unique to CYTODYN," and that in her experience the FDA does not typically "monitor press releases and tell [Sponsors] to correct all of them." Ms. Sheikh further recalled the FDA having informal meetings and discussions about Cytodyn's press releases, including discussions about inconsistent data on Leronlimab posters someone saw at an HIV conference.

[2] *See generally* Justice Manual, 9-5.002 "Criminal Discovery." https://www.justice.gov/jm/jm-9-5000-issues-related-trials-and-other-court-proceedings. ("[A]ll potentially discoverable material within the custody or control of the prosecution team should be reviewed… With respect to outside agencies, the prosecutor should request access to files and/or production of all potentially discoverable material. The investigative agency's entire investigative file, including documents such as FBI Electronic Communications (ECs), inserts, emails, etc. should be reviewed for discoverable information… Prosecutors should also discuss with the investigative agency whether files from other investigations or non-investigative files such as confidential source files might contain discoverable information. Those additional files or relevant portions thereof should also be reviewed as necessary.").

[3] *See* December 20, 2022 U.S. Department of Justice press release featuring the following quote by FDA-OCI Assistant Commissioner Catherine A. Hermsen: "The FDA would like to extend our thanks to our *federal law enforcement partners* for sending a strong message to biotechnology executives and others that these types of actions will not be tolerated." https://www.justice.gov/opa/pr/two-biotech-ceos-charged-securities-fraud-schemes

[4] *See, e.g.,* Interviews of Erin Kate Barton (August 2, 2022); Brian Brothen (August 19, 2021, August 25, 2021, September 8, 2021, and November 9, 2021); Patrick Burke (September 7, 2022); Min Xiu Chen (July 14, 2022); Deborah Cole (July 20, 2022); Cristina De Leon (August 9, 2022); Carl Dockery (July 12, 2022 and September 13, 2022); Peter Frantz (July 20, 2022); Kazem Kazempour (July 7, 2021); Jacob Lalezari (December 16, 2021); Antonio Migliarese (October 12, 2022); Michael Mulholland (July 20, 2021); Bruce Patterson (December 14, 2021); Nader Pourhassan (July 20, 2021); Virginia Sheikh (February 2, 2022); Sam Skariah (February 17, 2022); Suzanne Strayhorn (October 13, 2022); George Bitar (August 4, 2022); Mahboob Rahman (May 25, 2021 and June 14, 2021); Russell Munves (September 27, 2021); Prasanta Patel (July 14, 2022); Joseph Meidling (July 19, 2022); Robert Constant (December 14, 2022); Mehrnoosh Hadadi (July 5, 2022); Dennis Burger (October 3, 2022); Kush Dhody (November 11, 2022); Alan Rowland (February 9, 2022); Nitya Ray (October 11, 2022); Richard Pestell (November 11, 2021); Victoria Martin (October 13, 2022); Abby Ho (August 25, 2022); Christine Corrado (October 4, 2022); and Anthony Caracciollo (June 23, 2022).

The government is also required to search for and provide these records because it is undisputed that the FDA's role is of central relevance to this case and the Government had extensive access to both FDA records and personnel in conducting its investigation.[5] This access obligates the Government to carry out the requested searches of FDA files and produce the requested document and information. Multiple federal courts have held that the government cannot pivot from having ready access to the files and employees of a particular federal agency of prime relevance to a case to then disclaiming any ability or obligation to obtain and produce requested records from that agency. *See U.S. v. W.R. Grace*, 401 F. Supp. 2d 1069, 1078-79 (D. Mont. 2005) (holding the prosecution was in possession, custody, or control of documents that were in the physical possession of government agencies that were not part of a criminal investigation jointly undertaken by the Department of Justice and the Environmental Protection Agency, but who had provided files to the prosecution team and allowed their employees to be interviewed by the prosecution as part of that investigation); *U.S. v. Libby*, 429 F. Supp. 2d 1, 11 (D.D.C. 2006) (holding that the Office of the Vice President and the CIA contributed significantly to the investigation and eventual indictment of the defendant, and concluding the government had knowledge of and access to documents from those offices responsive to the defendant's request for Rule 16 purposes); *U.S. v. Naegele*, 468 F. Supp. 2d 150, 154 (D.D.C. 2007) (compelling the government to obtain and disclose the Office of the U.S. Trustee file regarding the agency's decision to deny the defendant's bankruptcy petition, including directing the government to search the files of the main office of the U.S. Trustee and any other files where the requested information might likely be found); *see also United States v. Deutsch*, 475 F.2d 55, 57 (5th Cir. 1973), *overruled on other grounds by United States v. Henry*, 749 F.2d 203 (5th Cir. 1984) ("[T]here is no suggestion in *Brady* that different 'arms' of the government, particularly when so closely connected as this one for the purpose of the case, are severable entities.").

The documents and correspondence requested above are within the government's possession, custody, or control and are material to the preparation of Dr. Kazempour's defense. We request that you produce the requested documents no later than October 1, 2023. Please let us know if you have any questions.

Ben A. O'Neil
McGuireWoods LLP

Counsel for Kazem Kazempour

[5] *See, e.g.*, June 2022 communications between HHS-OCI SA Maridehl Mather and Suzanne Strayhorn discussing FDA communications, in which SA Mather tells Ms. Strayhorn that the "prosecutor is now asking for [specific communication documents]." (DOJ-PROD-0003434151).